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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,844	12/31/2003	Anil Chatterji	C261 1070.1	2825

26158 7590 01/17/2006

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EXAMINER

PUTTLITZ, KARL J

ART UNIT PAPER NUMBER

1621

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/748,844

Applicant(s)

CHATTERJI ET AL.

Examiner

Karl J. Puttlitz

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 and 29-49 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8,11,14,17-21,29-31,34-38,41,44 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-21 and 29-48 in the reply filed on 10/25/2005 is acknowledged. Pursuant to the species requirement, Applicant has elected those compounds conforming to Structure 1 in claim 2, and compositions comprising the same. Applicant has indicated that claims 1, 2, 5, 8, 11, 14, 17, 21, 29-31, 34-38, 41, 44 and 47 are readable on the elected invention. Accordingly, claims 3, 4, 6, 7, 9, 10, 12, 13, 15, 16, 22-28 (canceled), 32-33, 39, 40, 42, 43, 45, 46, 48 and 49 are non-elected. However, the examiner will rejoin claims 18-20 as readable on the elected invention since these claims are drawn to compounds within the elected species. Consequently, claims 1, 2, 5, 8, 11, 14, 17-21, 29-31, 34-38, 41, 44 and 47 are treated on the merits herein. A reasonable number of species will be rejoined upon indication of an allowable genus.

### ***Claim Objections***

Claims 5, 11, 14, 38, 44, and 47 are objected to because of the following informalities:

These claims recite species within brackets,; i.e.; "[ ]". The brackets should be removed so as not confuse with claim amendmewnts removing subject matter from the claims.

Help helping in claim 30 is a typographical error.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

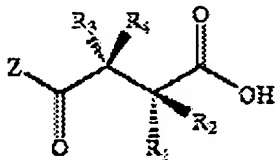
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, 8, 11, 14, 17-21, 29-31, 34-38, 41, 44 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites compounds of the formula



Wherein  $n1 = n2 = 1$  to 8. However, this would exceed the valency of the carbon to which the R groups are attached. Also, it is unclear as to how many R groups are in the compound, and the definitions of these groups. Conversely, if the R groups are not attached to carbon, then the formula of Structure 1 in claim 2 would not conform:



Structure 1

since the R groups in claim 2 are not recited in claim 1 and carbon is not in the definitions of the R groups. This same relationship is in composition claims 29 and 31.

Claims 1 and 2 recite "and non-toxic salts". This would imply a composition, whereas these claims are compound claims.

Claim 2 recites that  $R_1$  to  $R_4$  is H,  $NH_2$ ,  $SO_3H$ , or  $OSO_3H$  . . . . It is unclear if the R groups can comprise all of the listed groups or some of them. In this regard, the examiner directs Applicant to M.P.E.P. § 2173.05(h) for claiming chemical groups in the alternative ("When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper."). This portion of the rejection also applies to those claims reciting species, e.g., claims 5, 11, 14, 38, 44 and 47.

In claim 17, the term "the cell surface densities" lacks antecedent basis.

Claim 18 recites a fold of increase without specifying the amount of the increase. The term "molecules of cells stimulated" does not make sense. The term "the fold" lacks antecedent basis.

Claim 30 requires that the instant compounds provide more efficient and faster presentation of antigens to T-cells. These conditions are terms of degree, and those of ordinary skill would not be apprised of the scope of the claim since there is no point of reference in the specification.

Claim 31 lacks definitions of the groups in Structure 1.

Claim 36 recites "different divalent metal cations such as Mg, Ca and Zn". It is unclear if the claim is required to have one or more of the listed cations.

Claim 37 recites derivatives of amino acid/dicarboxylic acid derivatives and their pharmaceutically acceptable selected alkali/alkaline earth metal salts. It is unclear which acids or derivatives Applicant intends to cover, or which salts are intended by the term "selected".

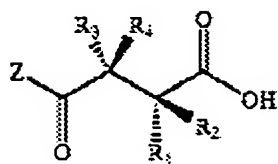
In claim 41, it is unclear which compounds in claim 2 Applicant intends to include in the recited composition, without specifically reciting the structure, or its defined groups.

### ***Prior Art Rejections***

The claims are drawn to, inter alia, Compounds of the general formula:



More particularly, the elected claims cover compounds of the following general formula:



Structure 1

See definitions in claims 1 and 2.

The claims also cover specific sub-geni (claim 8) and species of the above structures.

The claims also cover those embodiments wherein incubation of BM leukocyte precursors with different concentrations of the compound increases the cell surface densities of CD11c, CD80, CD54 and CD11c to various levels with maximum up regulation at 200 mM.

The claims also cover those embodiments wherein the claimed compounds give a fold increase in the levels of molecules of cells stimulated with either 15 ng/ml of GM-CSF or 200 mM of the synthetic compound at 48 h of incubation.

The claims also cover those embodiments wherein the claimed compounds are capable of inducing differentiation of dendritic cells and modulation of immune response controlled by dendritic cells.

.The claims also cover those embodiments covering compositions comprising the claimed compounds, useful as vaccines, which is nontoxic to monocytes and macrophages. The claims also cover those embodiments where the compositions provide more efficient and faster presentation to T-cells

Notwithstanding the clarity issues set forth in the rejection under section 112, second paragraph above, and based on the broadest reasonable interpretation of the claims, the following prior art rejections are entered below:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

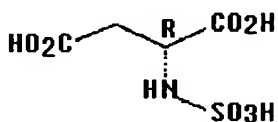
Claims 1, 2, 34, 29, 31, 35 and 37 rejected under 35 U.S.C. 102(b) as being anticipated by Lehninger et al., Principles of Biochemistry, 1993, p. 70 (Lehninger).

Lehninger teaches aspartic acid. The references also indicates that aspartic acid is an amino acid from which proteins of all organisms are built (claim 37).

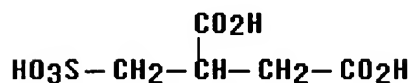
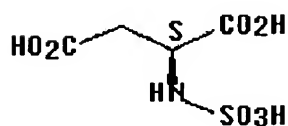
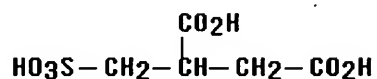
The foregoing anticipates those compounds and compositions covered by the rejected claims within the meaning of section 102.

Claims 1, 2, 5, 8, 11, 14, 17-21, 29-31, 34-38, 41, 44 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Dennis et al., "Ligand interactions at the active site of aspartate transcarbamoylase from Escherichia coli", Biochemistry (1986), 25(7), 1605-11 (Dennis).

Dennis teaches the following compounds:







See, for example, page 1607. Note that these compounds were prepared in less than 100%, suggesting presence of an amino acid starting material in the reaction product (claim 37).

The foregoing anticipates those compositions and compounds of the rejected claims within the meaning of section 102.

Claims 1, 2, 5, 8, 9, 11, 14, 29, 31, 34-36, 38, 41, 44 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,271,200 to Modi (Modi).

Modi teaches that sulfosuccinates (aspartic acid sulfates) are included as membrane-mimetic amphiphiles in drug delivery systems for macromolecules, such as vaccines, see column 4, lines 13-20. The term "sulfosuccinate" implies salts forms of the compound.

The foregoing anticipates those compounds and compositions of the rejected claims within the meaning of section 102.

### ***Claim Rejections - 35 USC §§ 102, 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-21 and 30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Modi and Dennis.

The rejected claims cover those embodiments of the instant invention wherein the instant compounds or compositions wherein incubation of BM leukocyte precursors with different concentrations of the compound increases the cell surface densities of CD11c, CD80, CD54 and CD11c to various levels with maximum up regulation at 200 mM.

The rejected claims also cover those embodiments of the instant invention wherein the instant compounds or compositions give a fold increase in the levels of molecules of cells stimulated with either 15 ng/ml of GM-CSF or 200 mM of the synthetic compound at 48 h of incubation.

The rejected claims also cover those embodiments of the instant invention wherein the instant compounds or compositions are capable of inducing differentiation of dendritic cells and modulation of immune response controlled by dendritic cells.

The rejected claims also cover those embodiments of the instant invention wherein the instant compounds or compositions are capable of more efficient and faster presentation of antigens to T-cells.

Neither Modi nor Dennis explicitly teach these aspects of the disclosed compounds. However, the requirements set forth in the rejected claims are properties of those compounds described by the applied references, and therefore, given the identity between the claimed compounds and those described in the applied references, these properties are anticipated or prima facie obvious, since separating a know compound from its properties is untenable, see M.P.E.P. 2112.01 ("Products of identical chemical composition can not have mutually exclusive properties." A chemical

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composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a *prima facie* case of unpatentability of Spada's polymer latexes for lack of novelty.").

Claims 17-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lehninger.

The rejected claims cover those embodiments of the instant invention wherein the instant compounds or compositions wherein incubation of BM leukocyte precursors with different concentrations of the compound increases the cell surface densities of CD11c, CD80, CD54 and CD11c to various levels with maximum up regulation at 200 mM.

The rejected claims also cover those embodiments of the instant invention wherein the instant compounds or compositions give a fold increase in the levels of molecules of cells stimulated with either 15 ng/ml of GM-CSF or 200 mM of the synthetic compound at 48 h of incubation.

The rejected claims also cover those embodiments of the instant invention wherein the instant compounds or compositions are capable of inducing differentiation of dendritic cells and modulation of immune response controlled by dendritic cells.

Lehninger fails to explicitly teach these aspects of the disclosed compounds. However, the requirements set forth in the rejected claims are properties of those compounds described by the applied references, and therefore, given the identity between the claimed compounds and those described in the applied references, these properties are anticipated or prima facie obvious, since separating a known compound from its properties is untenable, see M.P.E.P. 2112.01 ("Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a *prima facie* case of unpatentability of Spada's polymer latexes for lack of novelty.").

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at telephone number (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Karl J. Puttlitz  
*Assistant Examiner*

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,4,6,7,9,10,12,13,15,16,32,33,39,40,42,43,45,46,48 and 49.